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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,562	02/27/2004	Chul-Wook Kim	P/4535-4	9102
2352	7590	08/11/2006	EXAMINER	
OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			KAPUSHOC, STEPHEN THOMAS	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 08/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/788,562

**Applicant(s)**

KIM ET AL.

**Examiner**

Stephen Kapushoc

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

Claims 1-3 are pending and examined on the merits.

#### ***Specification***

1. The disclosure is objected to because of the following informalities:

The specification contains several typographical errors. See for examples: p.11 ln.3 where the specification uses the word 'slid' where the word 'slide' is likely intended; p.19 ln.6 where the specification reads '13 genes include expressed in ESF include troponin -C, L-lactate', where the first instance of the word 'include' may be removed. Applicant is requested to further examine the specification and correct any identified typographical errors.

Appropriate correction is required.

#### ***Information Disclosure Statement***

2. The listing of references in the specification is not a proper information disclosure statement (see for example reference cited within the text of the specification p.1 ln.26). 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Claim Objection***

3. Claim 3 is objected to because there is no period at the end of the claim. See MPEP 608.01(m). Appropriate rejection is required.

***Claim Rejections - 35 USC § 112 2<sup>nd</sup> – Indefiniteness***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are unclear over recitation of the phrase 'comprising a probe comprising fat specific genes' in claim 1. A 'probe' is typically defined in the art as an individual nucleic acid. It is thus unclear how a 'probe' (i.e. singular form) can detect specific genes (i.e. a plurality of genes). The claim may be made clearer if the term 'probe' is replaced with the phrase 'set of probes', if that is in fact what applicant intends.

Claims 1-3 are unclear over recitation of the phrase 'fat specific genes specifically expressed in the muscle and fat tissues' in claim 1. It is unclear if applicant intends a chip comprising genes only expressed in fat tissue, or expressed in some particular measure in muscle tissue and fat tissue. It is not known if, for example, a gene expressed only in fat tissue would be considered a 'fat specific' gene 'specifically expressed in the muscle and fat tissues'.

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Claim 2 is unclear over recitation of the phrase 'the probe DNA' as there is no antecedent basis for any 'probe DNA' in the claim. The claim may be made clearer if 'the probe DNA' is changed to 'the probe'.

Claim 2 is unclear over the recitation of various protein names in reference to elements included in 'the probe DNA'. It is unclear if Applicant intends, for example, that the probe DNA is some how associated with the collagen protein or if the probe DNA encodes a polypeptide that is a collagen.

Claim 3 is unclear over recitation of the phrase 'the functional cDNA chip having fat specific genes according to the growing stages in swine' in reference to a component of a kit, as there is no antecedent basis for any chip having fat specific genes 'according to the growing stages in swine' in the claim. The claim may be made clearer if 'the functional cDNA chip having fat specific genes according to the growing stages in swine' is changed to 'the functional cDNA chip having fat specific genes'.

Claim 3 is unclear over recitation of the phrase 'the tissue to be screened' as there is no antecedent basis for any 'tissue to be screened' in the claim. The claim may be made clearer if 'the tissue to be screened' is changed to 'a tissue to be screened'.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> Written Description***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the revised interim guidelines on written description published January 5, 2001 in the Federal Register, Volume 66, Number 5, page 1099-111 (also available at [www.uspto.gov](http://www.uspto.gov)).

The claims are drawn to a cDNA chip comprising a probe wherein the probe comprises 'fat specific genes specifically expressed in the muscle and fat tissues of swine'. Claims 1 and 3 recite only the description that the genes comprising the probes are expressed in muscle and fat tissues. Claim 2 recites only the names of four genes which the probe DNA includes. The claims are thus broadly drawn to chips comprising probes for which no structural information is provided.

When the claims are analyzed in light of the specification, the instant invention encompasses chips comprising a large number of nucleic acid probes comprising an extremely wide variety of nucleic acid sequences. The claims encompass probes of any length and any nucleotide sequence. Claims 1 and 3 encompass chips comprising probes wherein the probes comprise any genes expressed at any level in any swine muscle or fat tissue. Even the probes of claim 2 are only broadly defined by a gene name, and thus may encompass probes directed to any genomic variants (e.g. gene splicing variants, polymorphisms and mutations including single and multiple nucleotide substitution, insertions, deletions, translocations and gene rearrangements) that are

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altered in any physiological condition. For example, while claim 2 recites the gene name 'collagen' the prior art of Madsen et al (2003) teaches that the porcine collagen gene contains several polymorphisms that are not addressed by the instant specification. Additionally, while the probe DNA of the chip of claim 2 'includes collagen', the instant specification teaches only that, for example, the sequence of EST No.SM541 was analyzed and the genetic information was identified from the database at NCBI (p.8 Ins.9-10) as NP\_000079 (Table 1, page 12), which is a GenBank locus describing the amino acid sequence of human alpha 1 type I collagen preproprotein. The specification does not teach any aspect of the actual EST No.SM541 nucleotide sequence. The claims are thus drawn to chips containing a plurality of nucleic acids probes that encompass an extremely large genus. Neither the claims nor the instant specification clearly define any sequence information or structural limitations regarding what is considered 'a probe comprising fat specific genes specifically expressed in the muscle and fat tissues of swine'. Nucleic acids of such a large genus have not been taught by the specification.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. The instant specification does not provide any description of the nucleic acid sequence of any of the probes used in the examples provided of the analysis swine gene expression.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than

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nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, while the specification provides general information about probe construction (pages 6-10), there is no guidance as to how one may *a priori* identify a probe or probe set that comprises 'fat specific genes specifically expressed in the muscle and fat tissues of swine'.

Applicants' attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In the instant application, the provided information regarding the GenBank accession loci of GenBank entries that are in similar, in some way that is not described, to the probes of the instant application does not constitute an adequate written description of the broad subject matter of the claims, and so one of skill in the art cannot envision the detailed chemical structure of the nucleic acids encompassed by the claimed methods, regardless of the complexity or simplicity of the method of isolation. Furthermore, reliance upon an external GenBank sequence for identification is similar to the recitation of a trademark, in that the GenBank accession number does not represent a fixed disclosure of a sequence, but instead refers to a record that is constantly able to be updated and modified. Adequate written description requires more than a

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reference to a polypeptide sequence that is in some way similar to a polypeptide encoded by the claimed nucleic acid. The particular nucleic acids are required.

In conclusion, the limited information provided regarding the nucleic acid probes of the claimed methods is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of a probe set comprising fat specific genes specifically expressed in the muscle and fat tissues of swine.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

***Claim Rejections - 35 USC § 101 and 112 1<sup>st</sup> Enablement***

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to a cDNA chip for meat quality evaluation and screening of specific genes.

The specification asserts that the claimed invention is useful for screening the expression profile of genes related to meat quality in a specific tissue (p.4 Ins.8-9), and may be applied to swine improvement with high meat quality and evaluation of meat quality according to breeds and tissues of swine (p.4 Ins.11-12; p.4 Ins.22-23).

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However, the specification does not teach how the claimed objective of meat quality evaluation would be accomplished through the use of the claimed invention, or how the screening of any specific genes would allow for evaluation of meat quality.

Furthermore, there is no teaching in the specification, nor any teachings in the prior art as to how the claimed cDNA chip, or any analysis of expression using the claimed chip would be specifically informative with regard to any evaluation of meat quality, or how such a chip may be used to screen specific genes in an evaluation of meat quality.

Additionally, there are no teachings as to specifically how one might use a chip wherein 'the probe DNA includes collagen, fibronectin, inhibitor of metalloproteinase 3 and integrin beta-1 subunit' to accomplish an evaluation of meat quality.

Thus the asserted utilities of meat quality evaluation and screening of specific genes are not considered specific or substantial because the claimed chip would not provide information that is relevant to, for example, meat quality evaluation.

Furthermore, the examination of specific genes would require further experimentation in order to reasonably confirm a real world use for the asserted utility. For example, there is no showing in the specification or the prior art that an analysis of gene expression using the claimed cDNA chip would result in the practice of any method that has a real world utility. The instant invention is an invitation to one of skill in the art to undertake further research and experimentation to determine whether in fact the claimed array has a real world utility.

Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Although the claims are drawn to products, this rejection is written to address the functional limitations that are recited in the claims; one would not know how to make and use the claimed cDNA chip 'for meat quality evaluation and screening of specific genes' comprising 'fat specific genes'.

#### **Nature of the invention and breadth of the claims**

The claims are drawn to a cDNA chip comprising a probe comprising any genes expressed at any level in the muscle and fat tissues of swine.

Claim 2 requires that the probe DNA specifically includes collagen, fibronectin, inhibitor of metalloproteinase 3, and integrin beta-1 subunit.

The claims encompass evaluation of any measure of quality of any meat from any animal and any screening of any specific gene.

The claims require knowledge of an association between results generated using the claimed cDNA chip and an evaluation of meat quality and a screen of specific genes.

#### **Direction provided by the specification and working example**

The specification of the instant application teaches that 4,434 EST sequences (identified in the specification only by an arbitrary 'EST No.', such as 'SM541') were prepared from muscle and fat tissues of a swine and that the 4,434 ESTs were arrayed

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on a slide (p.7 Example 1). The specification does not provide any information regarding the sequence of any of the ESTs. The specification teaches that the ESTs were cloned and their genetic information was identified from the database at NCBI (p.8), and provides tables in which the 'EST No.' is related to an 'Accession No.' and a 'Description'. The specification does not teach how, for any particular EST, a conclusion was reached regarding its related 'Accession No.' and 'Description'. For example, there is no teaching in the specification regarding any sequence for EST No. SM541, and to what degree this EST is similar to GenBank Accession NP\_000079 which would allow for a determination that EST No. SM541 is 'Collagen'. Thus, the specification does not in fact teach that EST No. SM541 is in any way specific for a swine 'collagen' gene, or specific for any single particular gene in swine.

The specification further teaches an expression ratio of differentially expressed genes, as determined by hybridization to the created array, between ESM (early stage muscle) and ESF (early stage fat) (Table 2, page 16). The ratio, described in Table 2 as 'ESF(30) / ESM(30)', is indicated in values ranging from '-8.6' to '+10.6'. However, there is no explanation of what the values mean with regard to expression levels in muscle or fat. The specification does not teach, for example, if a large positive number is indicative of expression in fat tissue or muscle tissue. And while the specification asserts that, for example, inhibitor of metalloproteinase 3 and integrin beta-1 subunit were specifically expressed in ESF and are thus 'fat specific genes' (p.20 Ins.6-8), Table 2 indicates that markedly different expression ratios for the two corresponding ESTs:

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the expression ratio for inhibitor of metalloproteinase 3 is '-2.6' and the expression ratio for integrin beta-1 is '+2.0'.

And while the specification provides the expression ratio for several swine ESTs identified by EST No., the specification makes no correlation between any measure of any EST expression level and any measure of any meat quality evaluation criteria.

**State of the art, level of skill in the art, and level of unpredictability**

While the state of the art and level of skill in the art with regard to creating a cDNA chip of known gene sequences is high, the level of unpredictability with regard to creating a cDNA chip with a particular functionality, such as 'for meat quality evaluation' is even higher.

The prior art of the PIC Technical Update – Meat Quality (2003) teaches that there are a number of variables that are considered when determining meat quality in prok, including color, pH, water holding capacity, and firmness and marbling. However, there is no teaching in the prior art as to how one might use a cDNA chip to determine any aspect of meat quality.

Additionally, because the claims are drawn to a chip for meat quality evaluation in any animal, it is relevant to point out that a chip for the evaluation of gene expression in one animal may not be appropriate for analysis of gene expression in any other animal. While it is generally held true that structure correlates with function, Bork et al (1993) teaches an analysis of sugar kinases, and indicates that very distinct proteins (with different three-dimensional structures and strikingly different sequence patterns) can catalyze chemically equivalent reactions of similar or identical substrates (p.31 -

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Abstract). Additionally, sequences that appear quite similar may in fact have very different functionalities. Such a possibility is exemplified by Juppner (1995), which teaches that despite significant structural conservation, rat, opossum, and human PTH/PTHrP receptor homologs display distinct functional characteristics (Abstract; pp.39S-40S). Thus it is highly unpredictable as to how one would make or use a chip comprising swine genes for meat quality evaluation in any other animal.

Furthermore, it is relevant to point out the breadth of the probes encompassed by the claims. For example, while claim 2 requires a probe including 'collagen', the instant specification points out that 'collagen' comprises at least 18 type of different macro protein groups (p.16 Ins.10-12). It is thus highly unpredictable as to whether or not any gene falling under the broadly encompassing name 'collagen' would in fact be a 'fat specific gene' or in any way useful in a chip for 'meat quality evaluation'.

Additionally, because the claims require a probe comprising 'fat specific genes', it is relevant to point out that the prior art of Cheung et al (2003) teaches that there is natural variation in gene expression among different individuals in a population. The reference teaches an assessment of natural variation of gene expression in lymphoblastoid cells in humans, and analyzes the variation of expression data among individuals and within individuals (replicates) p.422, last paragraph; Fig 1). The data indicates that, for example, expression of *ACTG2* in 35 individuals varied by a factor of 17; and that in expression of the 40 genes with the highest variance ratios, the highest and lowest values differed by a factor of 2.4 or greater (Fig 3). It is thus unpredictable as to whether or not any 'fat specific gene' in any particular animal would in fact be a 'fat

specific gene' in any other different animal.

#### **Quantity of experimentation required**

There would be a large and prohibitive amount of experimentation required to make and use the claimed invention. One would have to determine what expression level in a particular tissue is required to determine that any particular gene is a 'fat specific gene', and then identify 'fat specific' genes. One would further have to establish which 'fat specific genes' can be used to create a chip 'for meat quality evaluation', which would require establishing an association between the identified 'fat specific' genes and any measure of meat quality for any animal.

#### **Conclusion**

Taking into consideration the factors outlined above, including the nature of the invention and the breadth of the claims, the state of the art, the level of skill in the art and its high level of unpredictability, the amount of guidance by the applicant and the paucity of working examples, it is the conclusion the an undue amount of experimentation would be required to make and use the claimed invention.

#### ***Claim Rejections - 35 USC § 102***

In rejection of the claims in view of the prior art, the breadth of the claims is noted. The claims are drawn to a chip comprising probes wherein there are no defining structural limitations regarding the probes. Even in the case of claim 2, where the claim recites several gene names, there are no structural limitations, in either the claim or the specification, defining what is required to satisfy the limitations of the claim.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (1995 US Patent 5,474,796).

Brennan teaches a microarray that contains 10-mer polynucleotides spotted at discrete locations such that the total array represents every possible permutation of 10-mer oligonucleotide (col. 9, Ins. 48-55). Such an array would inherently comprise any 10-mer nucleic acid, including nucleic acids that satisfy the claims of the instant application.

Regarding claim 1, because of the comprehensive nature of the array of Brennan, the array of Brennan comprises a probe set comprising fat specific genes that are specifically expressed in the muscle and fat tissues of swine.

Regarding claim 2, considering the breadth of the claim and the lack of any structural limitations imparted by the recited gene names, the array of Brennan is an array where in the probe DNA includes collagen, fibronectin, inhibitor of metalloproteinase 3, and integrin beta-1 subunit.

12. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al (2001).

Yamamoto et al teaches the analysis of swine genomic DNA using a Southern blot wherein the genomic DNA is immobilized to a solid support.

Regarding claim 1, teaches swine genomic DNA immobilized on a substrate (Fig 1; p.3309, left col., first full paragraph), which is a chip. Because the blot taught by Yamamoto is a blot of genomic DNA, the blot of Yamamoto contains all of the swine genes of the genome, including fat specific genes specifically expressed in the muscle and fat tissues of swine.

Regarding claim 2, because the blot of Yamamoto contains the entire swine genome immobilized on a solid support, the blot of Yamamoto comprises probe DNA that includes collagen, fibronectin, inhibitor of metalloproteinase 3, and integrin beta-1 subunit.

13. Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Bai et al (March 1, 2003).

Bai et al teaches a porcine cDNA microarray. The reference teaches that inserts from two porcine  $\lambda$ ZAP-Express cDNA libraries (p.11, left col., Ins.8-11) were amplified to create probe DNA that was immobilized on a glass slide (p.11, left col., Ins.37-50).

Regarding claim 1, the array taught by Bai et al is a cDNA chip (a collection of cDNA-specific probes immobilized on a substrate of CMT-GAPS coated slides). Given the breadth of the requirements of the claim that the probe comprises genes expressed in the muscle and fat tissues of swine, wherein the expression can be at any level, the array of Bai et al satisfies the limitations of the claimed chip.

Regarding claim 3, Bai et al teaches a kit (i.e. a collection of compositions) including an array of swine cDNAs (p.11 – Construction of porcine skeletal muscle

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cDNA microarray) as well as probe cDNA created using the CyScribe First-Strand cDNA labeling kit (which inherently produces Cy5-dCTP or Cy3-dCTP to label cDNA produced from RNA) (p.11 – Red-white muscle microarray hybridisation), an Affymetrix 428 scanner (p.11 – Red-white muscle microarray hybridization, second paragraph), which is a fluorescence scanning system, and ImaGene v4.2 and GeneSpring v4.2 (p.11 – Microarray expression analysis and clone identification) which are computer analysis systems, for analysis of swine genes.

### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (1995 US Patent 5,474,796) in view of Li et al (2001).

Brennan teaches a microarray that contains 10-mer polynucleotides spotted at discrete locations such that the total array represents every possible permutation of 10-mer oligonucleotide (col. 9, Ins. 48-55). Such an array would inherently comprise any 10-mer nucleic acid, including nucleic acids that satisfy the claims of the instant application. Because of the comprehensive nature of the array of Brennan, the array of Brennan comprises a probe set comprising fat specific genes that are specifically

expressed in the muscle and fat tissues of swine. Thus Brennan teaches the chip of claim 1, as required by the limitations of the kit of claim 3.

Brennan does not teach Cy5-dCTP or Cy3-dCTP bound cDNA from RNA of a tissue, a fluorescence scanning system, and a computer analysis system.

Li et al teaches the analysis of genetic material using microarrays. The reference teaches the generation of probe material via RT-PCR using Cy3-dCTP and Cy5-dCTP (p.697-Probe preparation and multiplex PCR). The reference further teaches a fluorescence scanning system (e.g. ChipReader (Virttek) confocal scanners) and a computer analysis system (e.g. ImaGene software (Biodiscovery)) (p.697 – Hybridization and data analysis).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have combined the array of Brennan with the Cy5-dCTP or Cy3-dCTP labeled cDNA, fluorescence scanning system, and computer analysis system of Li et al so as to have created the kit of claim 3 of the instant application. One would have been motivated to do so based on the teachings of Li et al that DNA arrays can encode tens of thousands of possible target sequences and offer a simple way of storing and indexing numerous hybridization probes. Additionally, Li et al teaches that introduction of a Cy label into a nucleic acid using Cy3-dCTP or Cy5-dCTP is the simplest method for incorporating a label (p.697 – Probe preparation and multiplex PCR) and that such labels readily incorporate in PCR products (p.702 – left col., last paragraph). Furthermore, Li et al teaches that such labeled nucleic acid are easily detected using confocally based array readers (p.702, right col., Ins.3-6), and

demonstrates that an analysis system allows for the determination of signal intensities at hybridized positions on the array (Fig. 5; p.697 – Hybridization and data analysis).

### ***Double Patenting***

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1 and 3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/785,981. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and claimed subject matter.

Regarding claim 1 of the instant application, the claims of the conflicting application are drawn to a cDNA chip comprising a probe comprising genes in the muscle and fat tissues of swine. Given the lack of structural requirements in the claims of the instant application, the cDNA chip of the instant application is anticipated by the claims of the conflicting application.

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Regarding claim 3 of the instant application, claim 3 of the conflicting application is drawn to a kit comprising the same elements (Cy6-dCTP or Cy3-dCTP bound cDNA from RNA, fluorescence scanning and computer analysis systems) as the kit of claim 3 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1 and 3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/788,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and claimed subject matter.

Regarding claim 1 of the instant application, the claims of the conflicting application are drawn to a cDNA chip comprising a probe comprising genes expressed in the muscle and fat tissues of swine. Given the lack of structural requirements in the claims of the instant application, the cDNA chip of the instant application is anticipated by the claims of the conflicting application.

Regarding claim 3 of the instant application, claim 5 of the conflicting application is drawn to a kit comprising the same elements (Cy6-dCTP or Cy3-dCTP bound cDNA from RNA, fluorescence scanning and computer analysis systems) as the kit of claim 3 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/789,723. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and claimed subject matter.

Regarding claim 1 of the instant application, the claims of the conflicting application are drawn to a cDNA chip comprising a probe capable of detecting genes specifically expressed in swine muscle and fat tissues. Given the lack of structural requirements in the claims of the instant application, the cDNA chip of the instant application is anticipated by the claims of the conflicting application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claim 3 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10/789,723 in view of Li et al (2001).

Claim 3 of the instant application is drawn to a kit comprising a chip wherein the chip comprises a probe comprising genes expressed in the muscle and fat tissue of swine. The kit of claim 3 of the instant application further comprises Cy6-dCTP or Cy3-dCTP bound cDNA from RNA, fluorescence scanning and computer analysis systems.

Claim 10 of the conflicting application is drawn to a kit for screening and function analysis of swine genes comprising a chip comprising a probe capable of detecting genes expressed in the muscle and fat tissues of swine. Given the lack of structural requirements in the claims of the instant application, the cDNA chip of the instant application is anticipated by the claims of the conflicting application.

The conflicting application does claim a kit specifically comprising Cy6-dCTP or Cy3-dCTP bound cDNA from RNA, fluorescence scanning and computer analysis systems. However such elements were known in the art at the time the invention was made.

Li et al teaches the analysis of genetic material using microarrays. The reference teaches the generation of probe material via RT-PCR using Cy3-dCTP and Cy5-dCTP (p.697-Probe preparation and multiplex PCR). The reference further teaches a fluorescence scanning system (e.g. ChipReader (Virttek) confocal scanners) and a computer analysis system (e.g. ImaGene software (Biodiscovery)) (p.697 – Hybridization and data analysis).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have included the Cy5-dCTP or Cy3-dCTP labeled cDNA, fluorescence scanning system, and computer analysis system of Li et al in the screening kit of claim 10 of the conflicting application.. One would have been motivated to do so based on the teachings of Li et al, which teach that introduction of a Cy label into a nucleic acid using Cy3-dCTP or Ct5-dCTP is the simplest method for incorporating a label (p.697 – Probe preparation and multiplex PCR) and that such labels readily incorporate in PCR products (p.702 – left col., last paragraph). Furthermore, Li et al teaches that such labeled nucleic acid are easily detected using confocally based array readers (p.702, right col., Ins.3-6), and demonstrates that an

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analysis system allows for the determination of signal intensities at hybridized positions on the array (Fig. 5; p.697 – Hybridization and data analysis).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

21. No claim is allowable. No claim is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc  
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CARLA J. MYERS  
PRIMARY EXAMINER